Quo vadis - Reusable surgical instruments

Changes affecting reusable surgical instruments introduced by the new Medical Device Regulation (MDR) - Regulation (EU) 2017/745

ENGLISH

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The history of surgical instrument use

The use of surgical instruments has a long history. Procedures such as stemming the flow of blood from injuries, as well as the treatment of broken bones, infected wounds and chronic ulcers have been part of surgery's remit from the beginning. Evidence of surgical interventions where those being treated survived exists from as early as the stone age. Little is known as a whole about their success and recoveries. Surgical techniques have not been the exclusive domain of us humans (homo sapiens). An over 50,000-year-old neanderthal skeleton discovered in a cave in modern Iraq is a testament to arm amputation. It was in antiquity - during the time of Hippocrates - that classical surgery was developed. Surgical writings that serve as evidence from antiquity include the texts On Setting Joints and On Bone Fractures from the Corpus Hippocraticum (5th century BCE). Even back then, over 200 different instruments were employed during operations.

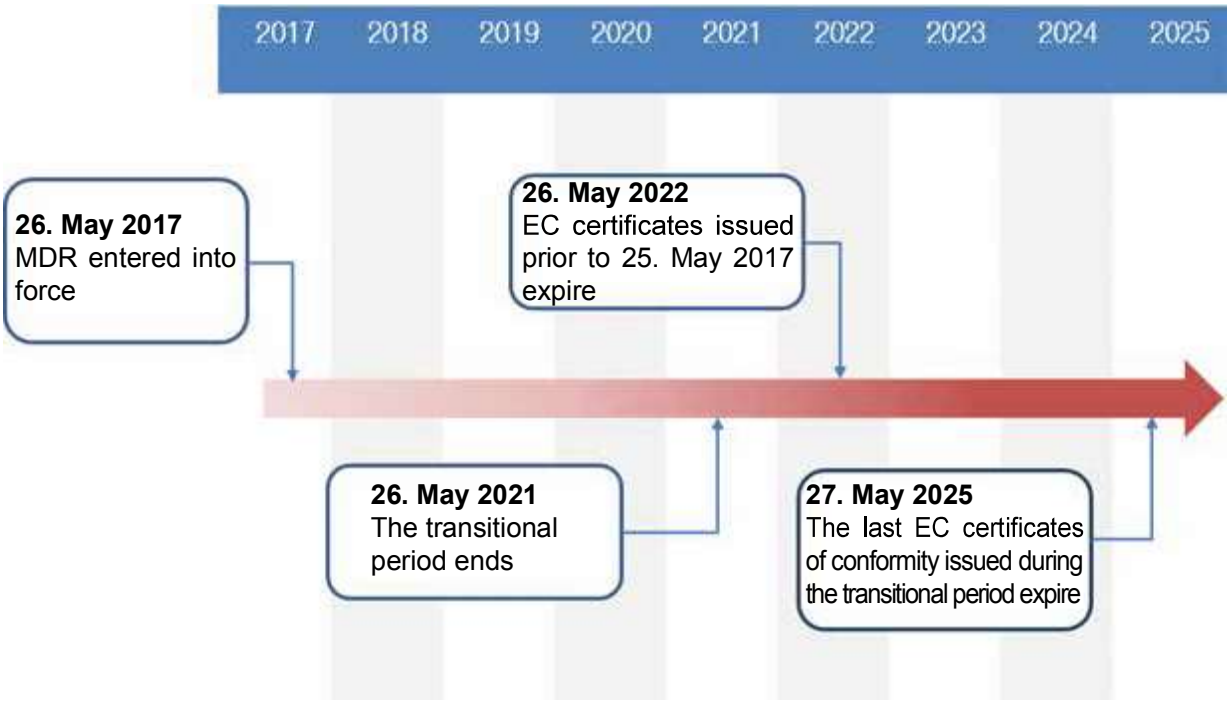
Obstetrical forceps by Adam Elias von Siebold (1775-1828)

From the Middle Ages until the early modern period, surgery was referred to in German as both “Wundarznei” (wound medicine) and “Chirurgie”, with the latter serving as the standard term to this day. Until the advent of academic surgery, operations were performed by barber surgeons - known in the military as “feldsher” (physician’s assistants) - who had received training in a skilled trade.

The 19th century saw the beginning of the large-scale production of instruments made from steel, with Gottfried Jetter, for instance, manufacturing surgical instruments in Tuttlingen from the year 1867. What started as a small workshop was rapidly expanded, quickly becoming famous for the quality of its instruments. Producing scalpels, scissors, tweezers and forceps in-house, the business would later adopt the name Aesculap and go on to define the entire region surrounding Tuttlingen. Metal instruments continue to dominate surgical treatment in European hospitals to this day, though single-use instruments made from stainless steel as well as plastic are gaining ground. The new legislative amendments will have a considerable influence on the number of manufacturers, the type of material and the use of surgical instruments going forward.

Challenges brought about by statutory requirements and changes

Today, as never before, all companies involved in the medical devices industry are having to contend with the headache caused by the introduction of the new MDR. The new EU Medical Device Regulation (MDR) was adopted by the European



MDR and transitional periods

Parliament on 5. April 2017. Following its publication in the EU Official Journal on 5. May 2017, the new regulation came into force on 25. May 2017 featuring a three-year transition period until 2020. During this period, certifications may be issued according to both the new regulation as well as the old directives. The long-established Council Directives 90/385/EEC and 93/42/EEC will subsequently no longer apply. The MDR specifies requirements pertaining to the development, production, use and monitoring of medical devices that pose significantly greater hurdles when compared with the previous legal position. Manufacturers are facing a variety of challenges as a result of these changes, particularly those concerning the content of technical documentation, clinical evaluations and post-market surveillance. The scope of the new requirements will lead in many instances to a longer, more strict conformity assessment procedure and consequently a longer time-to-market process for medical devices.

Due to the small number of notified bodies and the outbreak of the coronavirus pandemic, the entry into force of the MDR has been postponed by one year until 25. May 2021. A new regulation that replaces the two existing directives will not therefore be in place until 2021. While this means greater uniformity across the EU member states, it also entails less room for manoeuvre for individual companies. The MDR also makes no distinction based on whether the device is intended for a very large market or rarer illnesses. Exceptions for niche applications, e.g. in the case of small patient groups, are expected to be few and far between. Any firm that wishes to bring medical devices to market must in future meet the requirements under the new MDR regulatory framework.

This equally applies to the field of surgery and notably concerns all medical technology companies in and around Tuttlingen, with the MDR also specifying changes affecting reusable surgical instruments. Risk class I is expanded to include a new sub-category (class Ir) for reusable surgical instruments. The legislature has established more stringent requirements for these devices with respect to conformity assessment procedures. Manufacturers of relevant devices will be expected to have these recertified. The manufacturer must go through a procedure in accordance with either MDR Annex IX Chapter I (quality management system) or MDR Annex XI Part A (production quality assurance) with a notified body. For these devices, the notified body's participation in these procedures is, however, limited "to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and the related instructions for use."

Germany's federal government still has work to do before the final implementation of the MDR, with the regulation necessitating changes to domestic legislation. Legislative amendments will be made in Germany on the basis of so-called delegated acts. The German Federal Ministry of Health has set up the National Working Group on the Implementation of the MDR (NAKI) with this in mind. Two additio-

nal legislative acts need to be considered in Germany going forward:

1. The Medical Devices EU Amendment Act (Medizinprodukte-EU-Anpassungsgesetz, MPEUAnpG) - draft legislation passed by Germany's lower house of parliament, the Bundestag, on 05. March 2020

2. The Medical Devices Implementation Act (Medizinprodukte-Durchführungsgesetz, MPDG) and further legislative amendments (described in MPAnpG-EU)

The Medical Devices Amendment Act EU (MPEUAnpG) is designed to adapt the German Medical Devices Act (Medizinproduktegesetz, MPG) to the EU requirements that will then apply, i.e. primarily those set out in Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. These regulations together replace the three EU directives (90/385/EEC, 93/42/EEC, 98/79/EC) from the 1990s following transitional periods of 3 (medical devices) and 5 (in vitro diagnostic medical devices) years respectively.

Corrigendum II to Art. 120(3) MDR

The MDR was supposed to finally enter into force in May of 2020. As mentioned above, the appointed time has now been postponed by one year. Relief for manufacturers of class I devices has, however, already come in the form of the 2nd Corrigendum to the MDR (from 25. November 2019).
The original Article 120(3) [old version]

"By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and ..."

... now reads: Art. 120(3) [as amended]

"By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with either of those Directives, and ..."

This takes account of the current lack of notified bodies and additionally does away with differential treatment in relation to higher risk classes.

Manufacturers of class I medical devices according to the currently applicable MDD that will have to be allocated to a higher class under the MDR rules may (assuming MDD conformity) continue to be marketed until 26. May 2024. This applies to, among other things, reusable surgically invasive devices that come under (the new MDR) class Ir (Annex VIII, 5.2, Rule 6, second bullet point MDR) for which a declaration of conformity has been created in accordance with the MDD prior to 26. May 2020. This does away with the "final deadline" up to May of 2020 for the devices mentioned in Article 120(3).

Dr. Wolfgang Sening: "This was an important step in ensuring that existing devices, such as surgical instruments, can still be sold based on the previous regulatory conditions and will be a source of relief for clinics and hospitals worried about supply shortages."

One drawback: Should a material change (impact on compliance) be made to a device (brought to market under the MDD) after the date of application of the MDR, the modification and conformity are to be assessed according to the MDR rules, even during the extended transitional period.

Unique device identification (UDI)

The statutory regulations of the FDA and the new MDR requiring that all medical devices be labelled pose a further challenge. Reusable surgical instruments have their UDI carrier on the device itself. It is important that the UDI carrier be placed in such a manner that it can be read throughout the entire lifetime of the device, even if it is subjected to cleaning, disinfection and potentially sterilisation. The data is stored in the UDI database. Access is provided via the UDI-DI. The durability of the UDI / data matrix code affixed to the medical device must be verified in relation to the reconditioning cycle during the specified lifetime of the device. To this end, regulatory issues and durability tests have already been discussed and conducted by us with many clients.

As a result, an increasing number of surgical instruments are subjected to a defined cleaning and sterilisation cycle as a means of verifying the UDI code's durability (based on EN ISO 15883 and ISO 17665). From 26. May 2019, the GS1 (Global Standards One), HIBCC (Health Industry Business Communications Council) and the ICCBBA (International Council for Commonality in Blood Banking Automation) will serve as assigning bodies for UDI until the Commission has designated assigning bodies. UDI carriers will be mandatory for reusable surgical instruments from 26. May 2027 (in the case of class I devices).

Validation of class Ir instruments

The MDR has brought the professional reprocessing of medical devices, such as surgical instruments, for single or repeated use to the attention of regulatory and supervisory authorities as well as notified bodies. According to ISO 17664, manufacturers of instruments that fall under device class Ir must provide the user, e.g. in a clinic, with validated reconditioning methods.

Typical content of a validation plan (plan for worst-case validation)
- Designate the organisation, responsibilities and competencies for carrying out the validation process and the accompanying risk assessment.
- Define the person/team responsible for assessing the results protocols.
- Set out what device contamination / degree of device contamination is to be expected
- Justify and compare with worst-case devices
- Take into account the aspects mentioned above
- Identify the areas that are most difficult to clean
- Identify critical influences

The validation plan covers all stages of the reprocessing process, including descriptions of the respective procedures:
- Cleaning
- Disinfection
- Drying
- Functional testing and maintenance
- Packaging
- Sterilisation
- Functional testing

- Establish terms of acceptance / acceptance criteria and the basic methodology

Validation involves the devices being contaminated for test purposes in manner based on their use, subjected to the reprocessing step under investigation and subsequently tested for the presence of any residual contamination. Cleaning processes can normally be tested by contaminating with protein and blood (sheep's blood) that contains two detectable markers (protein and haemoglobin - as required by the FDA). The disinfection process can be validated by adding test microbes and then ascertaining the number of remaining microbes after cleaning. Steam sterilisation is validated by adding highly resistant microbes that ought to no longer be detectable following half a treatment cycle (half the normal duration of the sterilisation process). Further validation procedures range from particle analyses, cytotoxicity and accumulation tests, to examining the number of permissible reconditioning cycles.

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